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The Honorable Frank Pallone Chairman Committee on Energy and Commerce U.S. House of Representatives 2125 Rayburn House Office Building Washington, DC 20510

The Honorable Anna Eshoo Chairwoman Subcommittee on Health Committee on Energy & Commerce U.S. House of Representatives 2125 Rayburn House Office Building Washington, DC 20515 The Honorable Cathy McMorris Rodgers Ranking Member Committee on Energy & Commerce U.S. House of Representatives 2322 Rayburn House Office Building Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
Committee on Energy & Commerce
U.S. House of Representatives
2322-A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone, Chairwoman Eshoo, and Ranking Members McMorris Rodgers and Guthrie:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our views and recommendations in response to the March 31, 2021 letter from the House Committee on Energy and Commerce Subcommittee on Health, following up on the Committee's recent hearing entitled, "The Future of Telehealth: How COVID-19 is Changing the Delivery of Virtual Care." The AMA greatly appreciates the work the Committee is doing on this important issue to address patient access to health care services and physicians both during and after the COVID-19 pandemic.

Below are the AMA's responses to the follow-up questions posed by Representatives Lisa Blunt Rochester, Gus Bilirakis, Michael C. Burgess, and Richard Hudson:

Representative Lisa Blunt Rochester (D-DE)

1. How can Congress best support state Medicaid programs in their efforts to expand telehealth? Are there supports, incentives and learnings that federal policymakers could provide?

One way Congress can help support Medicaid programs is by continuing to support access to two-way audio-visual technologies and high-speed broadband infrastructure, which enable patients to access telehealth services. Access to telehealth services enabled by two-way audio-visual technologies can help reduce inequalities in care by increasing access for underserved populations, including patients with mobility or functional impairments that make travel difficult as well as patients who do not live near their physician or do not have reliable access to transportation. Medicaid patients in rural areas or minoritized populations in underserved urban communities often must travel long distances to access care, especially specialty services

including emergency and critical care. Telehealth also can help eliminate commutes to physician offices for those with mobility or transportation difficulties by providing care to patients directly in their homes. Physicians can also see patients with intermittent symptoms at the time these symptoms occur and can potentially provide improved care for conditions where seeing the patient's living environment can inform treatment plans. These advantages ultimately can help health systems and physician practices focus more on managing chronic diseases, enhancing patient wellness, improving efficiency, providing higher quality of care, and increasing patient satisfaction.

Patients cannot take advantage of telehealth services if they do not have the requisite internet connection to access them. Solving this requires enhanced funding for broadband internet infrastructure in rural areas and support for underserved urban communities and households to gain access to affordable internet access. The AMA strongly supports congressional efforts to expand high-speed broadband internet access to underserved communities.

Representative Gus Bilirakis (R-FL)

1. Currently, CMS requires that all Medicare patients be monitored for at least 16 out of 30 days as a condition of payment, except for COVID patients during the PHE. As an aspect of telehealth, do you believe that device-driven remote patient monitoring in the home, as CMS now describes and reimburses for it, is too strict in terms of the required time of monitoring and limits use cases or provider discretion and should be more flexible; and, if so, what guardrails, if any, should remain for care quality and program integrity?

The AMA strongly supports the Centers for Medicare and Medicaid Services' (CMS) continued use and payment of Current Procedural Terminology[®] (CPT[®]) codes 99453, 99454, 99457, and 99458 which were developed to describe the professional and technical components of remote physiologic monitoring (RPM) and management. CMS support of these services has had a tremendous impact on expanding access for patients in need of remote monitoring services.

The RPM codes were developed through concerted and thoughtful deliberations with input from nationally recognized clinical experts in digital medicine services as well as coding, valuation, and coverage. The AMA's Digital Medicine Payment Advisory Group (DMPAG) requested creation of these new codes by submitting an application to the CPT Editorial Panel. The Panel, with input of the national medical specialties, worked through the thoughtful CPT and AMA/Specialty Society RVS Update Committee (RUC) processes and ultimately approved these new codes. The DMPAG aggregated and conducted in-depth interviews with national flagship health systems and providers deploying these services and evaluated significant supporting meta-analysis of clinical trials establishing clinical benefit. An existing body of evidence exists, which was relied upon in making such recommendations, demonstrating that these services will increase value and improve patient health outcomes, particularly for patients with multiple comorbidities, chronic conditions, those facing access barriers due to geography, limited mobility, and those who are medically fragile.

The AMA is supportive of efforts to ensure that physicians can use codes as appropriate and necessary to reflect practice and patient needs. The AMA supports the use of CPT to describe all physician services and

the CPT Editorial Panel remains open to receiving any applications from stakeholders to implement changes in coding to describe monitoring periods for RPM treatment and management services.

1. Do you support retaining HHS authority to more robustly allow services delivered through telehealth after the COVID-19 public health emergency ends? Should that authority include waiving restrictions that exist outside the PHE on the types of providers who can furnish those services?

The AMA believes it is critical that the geographic and origination restrictions in section 1834(m) of the Social Security Act be removed, which would allow the Department of Health and Human Services (HHS) and, specifically, CMS to continue to provide access to all covered telehealth services after the end of the public health emergency (PHE). The flexibilities granted to CMS to provide greater access to telehealth during the pandemic have led to a marked increase in usage as patients could, for the first time, access telehealth services from wherever they are located, including their home, regardless of where they reside in the country. Since CMS lacks the statutory authority to permanently remove the geographic and originating site restrictions, Congress should expeditiously pass S. 368/H.R. 1332, the Telehealth Modernization Act. Enactment of this bipartisan legislation would eliminate the geographic site restrictions and reclassify an originating site to be wherever the patient can access the telecommunications system, an important solution to ensure that all patients can utilize two-way audio-visual care regardless of where they live.

Telehealth services have been critical during the PHE to ensure access to medical care while allowing for social distancing to avoid exposure and transmission of COVID-19, but the ability to use these services widely has also demonstrated a number of promising use cases, particularly for patients in need of chronic care management. Telehealth provides ready access to care for patients with mobility or functional impairments or other problems that make travel difficult and facilitate care for patients who do not live near their physician or have unreliable access to transportation. It allows physicians to see patients with sporadic symptoms at the time these symptoms occur and improves care for conditions where seeing the patient's living environment can inform treatment plans. Telehealth also facilitates team-based care by allowing other physicians, caregivers, and family members to join patient visits from their own location.

The AMA supports the physician-led team-based approach to care. Whether services are provided in-person or via telehealth, health care services should be subject to state scope of practice laws, supervision requirements, and proper access to physicians. Some of the current PHE expanded guidelines should be allowed to sunset to adhere to these preexisting laws/requirements. We support amendments to current law that would grant HHS unrestricted authority to make determinations as to which providers should be eligible to provide telehealth services rather than on a case-by-case basis through statute.

1. According to a Pew report, 15 percent of the American population own a non-smartphone cell phone and that number jumps to 24 percent in rural areas. Additionally, many seniors or those with disabilities struggle with video platforms and access to stable broadband. Do you support audio-only telehealth and as a physician, are you able to deliver high-quality care via a phone call? Shouldn't there be equal recognition of information gleaned from a video call and an audio call?

Yes, the AMA supports coverage for audio-only services and has called on CMS to continue this coverage after the public health emergency ends. While audio-only services are often not the first choice to deliver care, there are numerous patients and entire communities that have no access to the internet connectivity necessary to utilize audio-visual telehealth services in their homes. There are also medical practices that do not have sufficient connectivity to provide audio-visual telehealth services. Patients who cannot utilize audio-visual telehealth services include those in communities lacking broadband access, those where the technological capabilities are present but the patient cannot afford it, and others who have access to the technology and the connectivity but do not know how to use it. Inability to use audio-visual telehealth services is also a matter of health equity. Too often it is the same communities that face other barriers to good health outcomes who face technology barriers as well, such as Native Americans living on reservations and those in the rural south's Black Belt. But patients who cannot participate in audio-visual telehealth services are no less sick than those who can and it's important to their health care to retain access to these services.

- We've heard excellent testimony about how telehealth aided by the internet has helped bring doctors
 to patients wherever they are located during the pandemic. Of course, these doctors must be licensed
 to practice medicine in the state in which they reside. Before the pandemic and outside of DOD and
 VA health care, doctors also had to get and pay for a license where the patient was located, even
 though the science of medicine is the same.
 - a) How has easing of licensure rules expanded access to care for patients? As barriers came down, how have costs for doctors been reduced? Is there a reason to have a multiple-state licensure system?

State medical boards play a pivotal role in protecting the safety of patients through physician licensure, regulations, and disciplinary action. At the start of the COVID-19 pandemic, there was some concern that state licensing requirements would limit physicians' ability to quickly move into those areas hardest hit by COVID-19 and meet the workforce demands on the ground and via telehealth. In response to this concern, the states acted quickly to temporarily allow physicians to practice across state lines by waiving licensure or creating a streamlined licensure or registration processes in response to the COVID-19 emergency.

The AMA believes that it is essential to ensure that physicians and other health care providers are licensed in the state where the patient is located to provide telemedicine services. The AMA opposes proposals that would change which state is responsible for overseeing the physician from the state where the patient is located to the state where the physician is located. This changes which state medical practice and scope laws apply to the care rendered and raises serious enforcement issues as states do not have interstate policing authority and cannot investigate incidents that happen in another state.

Instead, AMA believes efforts should be made to increase membership in the Interstate Medical Licensure Compact (IMLC), a one stop-shop for physicians who are in good standing with their state medical boards to seek a license to practice in multiple jurisdictions in an expedited process. This maintains state-based licensure and the ability of state medical boards to protect the safety of patients, while allowing for greater sharing of information between states and expediting the licensure process for physicians who want to move between states or practice in more than one jurisdiction—whether in-person or via telehealth. To date, 30

states plus DC and Guam are members of the IMLC and eight more states have introduced legislation this year to join the IMLC.

- 1. On August 14, 2020, CDC reported that rates of substance abuse, anxiety, severe depression, and suicidal ideation increased across many demographics. Of grave concern, the report indicated that over 1 in 4 young adults had recently contemplated suicide. Additional research revealed that over 40 states saw a rise in opioid-related overdose deaths since the start of the pandemic. Overall, mental health conditions were the top telehealth diagnoses in the nation in November 2020 signifying an almost 20% increase year over year, with no indication that this trend is reversing.
 - a) Can you speak to the role that telehealth flexibilities such as the ability to serve a patient in their home and provide audio-only services, particularly for addressing mental health and substance use disorder have provided during this time?

Telehealth and audio-only services have been critical during the PHE to ensure access to necessary medical care while allowing for social distancing to avoid exposure and transmission of COVID-19, as well as preserving limited supplies of personal protective equipment, particularly early on in the pandemic. Mental health and substance use disorder treatment have proven to be great use cases for both telehealth and audio-only services and coverage and payment of these services along with all other telehealth and audio-only services CMS determines appropriate for coverage should continue past the end of the PHE.

Pursuant to authority granted under the CARES Act, the Drug Enforcement Administration (DEA) has allowed physicians to prescribe controlled substances based on telehealth visits between patients and their physicians and has allowed medications for the treatment of opioid use disorder, specifically buprenorphine, to be prescribed based on telehealth visits. Surveys of physicians with an X-waiver to prescribe buprenorphine have found that these flexibilities were extremely valuable in allowing them to continue to treat their patients during the COVID-19 pandemic. The AMA has urged the DEA to keep these flexibilities in place at least until the end of the nation's drug overdose epidemic.

Pursuant to authority granted under the CARES Act, CMS waived the requirements of section 1834(m)(1) of the Social Security Act and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology for certain services. This has allowed the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services. Expanded use of audio-visual telehealth services during the pandemic has made it clear that requiring the use of video limits the number of patients who can benefit from telecommunications-supported services, particularly lower-income patients and those in rural and other areas with limited internet access. It would be inappropriate to prevent these patients from accessing such services. In addition, we have heard from many physicians about the need to have access to audio-only services because a number of their patients, even those who own the technology needed for two-way real-time audio-visual communication, do not know how to employ it or for other reasons are not comfortable communicating with their physician in this manner.

The AMA believes that audio-only services are an important part of a fully integrated care plan and that physicians should permanently be able to deliver E/M (evaluation and management) services by telephone to patients who need a telecommunications-based service in the home but who do not have access to a video connection or cannot successfully use one. Without access to an audio-only option, limitations in internet and/or technology access as well as lack of experience with its use will increase inequities in access to medical care and widen disparities in health outcomes.

- 1. Should HHS consider expanding the types of audiology, speech-language pathology, physical therapy, and occupational therapy services that can be provided during the PHE if they are clinically appropriate and can be delivered with the same efficacy as in-person visits?
- 2. Do you believe Congress should consider allowing audiologists and members of the therapy professions to provide telehealth services under Medicare permanently when clinically appropriate, especially since they are currently doing so during the public health emergency and patients appear satisfied to receive services in this manner?

While we want to ensure that these decisions adhere to the physician-lead health care model and state scope of practice laws and supervision requirements where applicable, the AMA supports amendments to current law that would grant HHS unrestricted authority to make coverage and payment decisions for telehealth services, including determining what providers can provide telehealth services the same way they can for services provided by any other modalities. We believe this determination should be made by HHS and not made on a case-by-case basis by Congress through statute.

- 2. All I think you would agree that the earlier the identification of deteriorating patient condition, the better the chance of a positive outcome, and that we need to find a way to harness the spread of disease, especially in vulnerable patient populations such as the elderly and those with chronic medical conditions.
 - a) Chronic diseases place immense strain on the operation of our health system. Could you discuss how remote monitoring is used today, in addition to telehealth, to help in the care of those living with chronic conditions like diabetes, hypertension, asthma or kidney disease?
 - b) Do you support the use of remote patient monitoring that enables the early identification of physiologic changes in patient conditions in time to prevent catastrophic injury or death?
 - c) Would you agree that the recent use of remote patient monitoring tools that have helped clinicians, nursing homes and hospitals respond to COVID 19 should be continued with appropriate Medicare coverage and reimbursement even when this current crisis is over?

The AMA agrees that the use of remote patient monitoring (RPM) has been essential to ensuring continued high-quality care during the pandemic. RPM is a digital health solution that allows physicians and patients to extend their care program by recording and transmitting data outside the traditional health care environment. Physicians can review data and monitor chronic conditions without a patient traveling to a health care setting and intervene as necessary to implement changes in a patient's care plan. RPM is particularly effective in monitoring chronic conditions because it allows for long term tracking and visibility into a patient's day to

day lives rather than only taking a snapshot when the patient visits a physician's office. By collecting data over time, chronic conditions can be managed in a timely way and respond to observed changes in the patient's condition. Moreover, data generated through RPM can help facilitate conversations between patients and physicians concerning the impact of any changes around disease management and can facilitate patient engagement by providing them access to their data and perspective on how these markers impact their health.

Fortunately, RPM technologies are not subject to the section 1834(m) telehealth restrictions. The AMA has been and continues to be a strong supporter of the coverage, use, and adoption of RPM technologies. We agree that CMS should continue to cover and reimburse RPM services at appropriate rates beyond the end of the PHE. Patient's needs for remote monitoring and assessment, particularly for chronic conditions that benefit from long term data and sustained observation, will not end at the close of the pandemic, nor will the need for greater flexibility for physicians to deliver timely and effective care. The AMA strongly supports CMS' continued use and payment of CPT codes 99453, 99454, 99457, and 99458 which were developed to describe the professional and technical components of remote physiologic monitoring. CMS support of these service has had a tremendous impact on expanding access for patients in need of remote monitoring services.

a) Do you agree that by bringing the healthcare to the patient at home will increase access to affordable and quality healthcare for vulnerable patients and those in rural areas?

The AMA agrees that greater access to telehealth and remote patient monitoring services in the patient's home will help increase access to affordable and quality health care in underserved communities including rural areas. Access to telehealth services can help reduce inequalities in care for underserved communities by providing access to specialized services for patients regardless of where they are located. Patients in rural areas or underserved urban communities often have to travel long distances to access care, especially specialty services including emergency and critical care. Telehealth and remote patient monitoring services also can help eliminate commutes to physician offices for those with mobility or transportation difficulties.

In addition to ensuring coverage of these services, the AMA supports congressional efforts to expand high-speed broadband internet access to underserved communities. Patients cannot take advantage of telehealth services if they do not have the requisite internet connection to access them. Solving this requires enhanced funding for broadband internet infrastructure in rural areas and support for under-served urban communities and households to gain access to affordable internet access.

Representative Michael C. Burgess, MD (R-TX)

- 1. Ms. Blunt Rochester and I just reintroduced the TIKES Act. This bill requires the Centers for Medicare and Medicaid Services to issue guidance and best practices to states on the use of telehealth in Medicaid. It also includes a MACPAC report to assess gaps in access to telehealth.
 - a) Has COVID-19 led any states to be particularly innovative in utilizing telehealth in their Medicaid programs that might inform these best practices?

Medicaid patients should have assurances that care will continue to be available to them in a safe and convenient manner during and after the COVID-19 pandemic, including through telehealth. The AMA supports policies to expand Medicaid coverage, payment and access to services provided through telehealth, including coverage of services provided via telehealth on the same basis as comparable services provided inpersons, as well the removal of all unnecessary barriers to accessing telehealth. In addition, Medicaid policies should provide for the use of accessible devices and technologies, with appropriate privacy and security protections, for connecting physicians and patients. Medicaid coverage and payment policies should also ensure telehealth is a supplement to, not a replacement for in-person care when necessary, and ensure patients always have the opportunity to access care in-person if they choose. Likewise, to support continuity of care, Medicaid patients must have access to the same physician providing in-person care for services delivered via telehealth. Finally, it is imperative that Medicaid patients have access to the digital technologies and adequate high-speed broadband necessary to fully utilize telehealth.

a) Has COVID-19 exposed any gaps in access to telehealth for Medicaid or other populations?

Access to telehealth services still lags behind in underserved communities, particularly minoritized communities and urban and rural communities that do not have adequate high speed broadband infrastructure or access to two-way audio-visual technologies like a smart phone.

The AMA supports congressional efforts to fund additional programs enhancing access to telehealth services through greater access to two-way audio-visual technologies and investing in high-speed broadband infrastructure. These investments can help ensure that underserved communities can gain access to telehealth services which have the potential to decrease inequities in care by providing greater access to specialty services, reducing time spent traveling to physician offices, and providing greater flexibility for scheduling.

1. While it does not fit into the technical definition of telehealth, remote patient monitoring offers much promise for chronic disease patients. You mentioned in your testimony how access to real-time information related to a patient's social determinants of health can lead to better health outcomes and reduced care costs. Are there any patient populations that can particularly benefit from remote patient monitoring paired with in-person or telehealth visits?

A growing body of evidence exists demonstrating that remote patient monitoring services have the potential to increase value and improve patient health outcomes, particularly for patients with multiple co-morbidities, chronic conditions, those facing access barriers due to geography, limited mobility, and those who are medically fragile. In particular, RPM has been shown in a systematic review to improve outcomes for patients with diabetes, asthma, hearth failure, and hypertension, and has a myriad of promising potential future use cases. Ensuring access, coverage, and payment of these services is essential to help improve health outcomes across the nation.

¹ Pare, G, Clinical Effects of Home Telemonitoring in the Context of Diabetes, Asthma, Heart Failure, and Hypertension: A Systematic Review, J Med Internet Res. 2010 Apr-Jun 12(2): e21.

1. Dr. Resneck, in your written testimony you say that concerns over fraud, waste, abuse and over-utilization are "misplaced," but that the digital nature of telemedicine creates built-in monitors to protect against fraudulent practices. What are you and other physicians seeing in practice when it comes to tracking and billing for telehealth services?

In general, tracking and billing for telehealth services has been seamless. For example, the Medicare claims process allows CMS to effectively track and audit all telehealth services billed to Medicare via a specific modifier code (Modifier 95). The Modifier 95 describes "synchronous telemedicine services rendered via a real time interactive audio and video telecommunications system" and is applicable for all codes listed in Appendix P of the CPT manual. In other words, when billing and tracking any service that Medicare otherwise covers, the Modifier 95 is added in addition to a CPT code to clarify that the service is administered via a telehealth platform. The Modifier 95, along with listing the Place of Service (POS) code based on the location in which the in-person service would have normally been provided, is also applicable on an interim basis for telemedicine services rendered during the COVID-19 Public Health Emergency. The requirement to code with the Modifier 95 enables CMS to properly track and audit telemedicine services and is a powerful tool for rooting out fraud, waste, and abuse.

a) Are there differences in the experiences of physicians in value-based payment relationships compared to those reimbursed in a traditional fee-for-service?

Accelerated by the pandemic, the AMA believes we are entering an era of digitally enabled hybrid care, characterized by fully integrated in-person and virtually enabled care delivery models that 'hybridize' care delivery integrating both in person and virtual care into an integrated care plan rather than treating these modalities as independent parts of a patient's care plan. We believe digitally enabled care models will be developed across a broader range of clinical conditions and acuity levels. The integration of new digital health solutions such as video visits, remote monitoring, asynchronous telehealth, continuous and passive sensors, and AI into digitally enabled hybrid care models offers the potential to address the quadruple aim of enhancing patient experience, improving population health, improving health care providers' work life and reducing costs. In both value-based care and fee for service models, the emerging digital landscape is offering physicians unique opportunities to provide fully integrated care models for their patients, delivering greater value and convenience while achieving greater health outcomes. This evolution to digitally enabled hybrid care will fundamentally transform the virtual care value equation for provider organizations and payors, regardless of their coverage paradigm. Instead of focusing narrowly on whether a specific type of visit can be delivered virtually (the focus of most telehealth value discussions today), the attention will shift to how we can use innovative technologies to enhance overall episodes of care, blending a virtual and in-person experience in ways that improve access and experience for some patients while maintaining or improving quality and reducing long-term costs.

It is important to have a diversity of payment models that support innovations in the delivery of care and AMA has worked collaboratively to try to advance alternative payment models (APMs). However, the rapid and dramatic increase in telehealth seen in the past year was within the Medicare Fee for Service program, not because of APMs. HHS had the authority to waive the geographic and originating site restrictions on telehealth for APMs, Medicare Advantage plans, Center for Medicare and Medicade Innovation (CMMI)

demonstrations and state Medicaid programs for dual-eligibles prior to the COVID emergency but had not done so in a consistent and vigorous manner. The rapid adoption of telehealth shows that physicians will rapidly incorporate innovations into practice when the statutory and regulatory barriers are removed, both within APMs and the traditional fee for service and other parts of the Medicare program. Medicare should adopt APM proposals developed by practicing physicians as most of the APMs implemented to date have not broken down the barriers to value-based care in the traditional payment system.

Representative Richard Hudson (R-NC)

1. Dr. Resneck, there are unique considerations for children with complex medical conditions who must travel out-of-state to receive specialized care. These children and their families face several hurdles ranging from delays in treatment, administrative burdens, and financial and logistical issues associated with travel and lodging. Telehealth may be a valuable tool for these families to access care with fewer obstacles, but current policies are not always clear and vary by state. Can you speak to how telehealth policies can be improved to support these children and families, as well as their providers?

The sweeping expansion of Medicare and private insurers telehealth policies resulted in a substantial increase in the use of audio-visual tools and mobile devices to provide care during the pandemic to patients who are vulnerable to severe illness from COVID-19, who have mobility issues, and who are social distancing, but the ability to use these services widely has also demonstrated that the benefits of telehealth can extend far beyond the public health emergency. Telehealth technologies allow for greater patient access to physicians including beyond normal clinic hours, increase continuity of care between a patient and their primary provider, and, importantly, help overcome clinician shortages, especially for many specialties that may be in short supply in rural and other underserved populations.

The AMA strongly believes that incorporation of telehealth services as well as other remote-based care like RPM services will deliver value to the health care system by increasing efficiency in care and improve the lives of patients seeking care that they might not otherwise have ready access to in their area by allowing them to access these services from the comfort of their own home and avoiding traveling long distances in order to access specialized care. Likewise, the Interstate Medical Licensure Compact (IMLC) creates an expedited pathway for physicians, including subspecialists, to obtain licensure in multiple states thereby allowing them to expand their reach and care for patients in multiple states. With 30 states, plus DC and Guam as members of the IMLC, the IMLC is a viable option for physicians seeking to provide telehealth across state lines, while also preserving state-based licensure and strengthening public protections by facilitating the sharing of investigative and disciplinary information among state medical boards.

Thank you for considering the AMA's testimony and responses to the questions posed.

Sincerely,

Jack Resneck, Jr., MD

cc: James L. Madara, MD